

# CALIFORNIA REGIONAL WATER QUALITY CONTROL BOARD

## MEMORANDUM

**TO:** John H. Robertus  
Executive Officer

**ATTACHMENT 7  
AGENDA ITEM 14**

**FROM:** Hashim Navrozali, WRCE  
Industrial Compliance Unit

**DATE:** August 7, 2003

**SUBJECT: IDEC PHARMACEUTICALS CORPORATION (NIMO FACILITY)  
RESPONSE TO COMMENTS REGARDING  
TENTATIVE ORDER NO. R9-2003-0140.  
ITEM NO. 14**

The Regional Board received a comment letter from IDEC Pharmaceuticals Corporation (IDEC) regarding tentative Order No. R9-2003-0140. Brief paraphrases of the concerns listed in the letter and staff's response are provided below. The specific part of the tentative Order and Fact Sheet that is being commented upon is also identified. The agenda material includes a copy of the letter.

### **IDEC letter, dated July 30, 2003**

#### **Comment 1.**

**Fact Sheet:** *(page 1, paragraph 1 (Section 1 - Contact Information))*

The contact information (corporate address and phone number) listed for IDEC's in the Fact Sheet was not accurate.

IDEC's letter provided the updated corporate address and phone number.

**Response:** These corrections have been incorporated into the Fact Sheet.

#### **Comment 2.**

**Fact Sheet:** *(page 2, paragraph 4 (Section 3.A - Facility Site))*

The Fact Sheet indicated that the NIMO site is located on approximately 90 acres of land in the Ocean Ranch Corporate Center in Oceanside.

IDEC's letter indicated that although IDEC owns 90 acres of land in the Ocean Ranch Corporate Center, the NIMO site will be developed on 45 acres of the land.

**Response:** This clarification has been incorporated into the Fact Sheet.

**Comment 3.**

**Fact Sheet:** (page 2, paragraph 4 (Section 3.A - Facility Site))

The Fact Sheet indicated that the two main products that will be manufactured at the NIMO facility will be Rituxin® and ZEVALIN™.

IDEC's letter stated that it has not been determined what specific pharmaceutical products will be manufactured at the NIMO facility. IDEC has requested that names of specific drugs be removed. The Fact Sheet should state that the NIMO facility will be manufacturing monoclonal antibodies for cancer and autoimmune diseases.

**Response:** This change has been incorporated into the Fact Sheet.

**Comment 4.**

**Fact Sheet:** (page 3, paragraph 4 (Section 3.B - Biologics Manufacturing Process))

The Fact Sheet indicated that after final formulation (dilution with a final carrier solution), the purified pharmaceutical product manufactured at the NIMO facility will be held as a bulk liquid until such time that it is filled into sealed vials.

IDEC's letter has indicated that the Fact Sheet should state that the bulk liquid final fill operations into vials will not be conducted at the NIMO facility. These fill operations will be conducted at an offsite location.

**Response:** This change has been incorporated into the Fact Sheet.

**Comment 5.**

**Fact Sheet:** page 4, paragraph 2 (Section 4.A(1) - Primary City Water Treatment) &  
page 6, paragraph 2 (Section 4.A(5) - Combined Discharge Characterization)

The Fact Sheet indicated that IDEC submitted softener regenerate waste brine test data for representative sampling conducted at its San Diego (Torreyana) facility in order to estimate the concentration of metals and other pollutants contained in the brine discharges from the NIMO facility.

IDEC's letter indicated that the brine sampling was actually conducted at its existing New IDEC Clinical Operations (NICO) facility in Oceanside and not the Torreyana facility.

**Response:** This correction has been incorporated into the Fact Sheet.

**Comment 6.**

**Fact Sheet:** page 5, paragraph 2 (Section 4.A(2) - Pretreatment of Water for Injection)

The Fact Sheet did not mention the addition of sulfuric acid (for pH adjustment) to the softener units associated with the Water for Injection (WFI) pretreatment train.

IDEC's letter indicated that a 20% solution of sulfuric acid is added to one of the softener units associated with the WFI pretreatment train. The sulfuric acid is used to maintain the pH of the softener effluent in the 7 to 8.3 range. This range of pH will ensure proper functioning of the WFI vapor compression stills.

**Response:** The Fact Sheet has been modified to discuss the addition of sulfuric acid to the softener unit associated with the WFI pretreatment train.

**Comment 7.**

**Fact Sheet:** *page 8, paragraph 2 (Section 4.D - Stormwater Discharges)*  
**Tentative Order:** *page 6 (Finding 17)*  
*page 18 (Section F.5 – Notifications)*

The Fact Sheet and Tentative Order indicate that the SWRCB already processed IDEC's Notice of Intent (NOI) to comply with the *Statewide General Industrial Storm Water Permit* and assigned the NIMO site with a WDID identification number.

IDEC's letter states that IDEC has to date not filed an NOI for the *Statewide General Industrial Storm Water Permit* for its NIMO site. IDEC will be submitting an NOI to comply with the General Permit, once construction of the NIMO facility is completed. The WDID currently assigned to the facility by the SWRCB is for enrollment of the NIMO site in the *Statewide General Construction Storm Water Permit*.

**Response:** The Fact Sheet and tentative Order have been modified to reflect this change.

**Comment 8.**

**Tentative Monitoring and Reporting Program (MRP):**  
*page M-5, Section D (Part A - Offshore Water Quality Monitoring)*  
*page M-6, Section D (Part B - Benthic Monitoring)*  
*page M-5, Section D (Part C - Additional Biological Monitoring)*

The tentative MRP requires intensive monitoring of offshore water quality parameters, benthic communities/sediment characteristics, and demersal fish and macroinvertebrates, as part of the Receiving Water Monitoring Program (*Section D*). The MRP specifies that this monitoring shall be required during the 12-month beginning July 1, 2003 through June 30, 2004. This monitoring is required for all entities that route their effluent to the Oceanside Ocean Outfall for disposal to the Pacific Ocean. The MRP indicates that the receiving water and sediment monitoring program for the OOO may be conducted jointly by IDEC with the City of Oceanside, and any other agencies/dischargers utilizing the OOO.

IDEC has indicated in its letter that the July 2003 start date for the intensive monitoring of the receiving water/sediment parameters in the vicinity of the OOO should not be applicable to the NIMO facility, since the discharges from the facility are not expected to commence prior to late fall of 2003.

**Reponse:** The intensive receiving water/sediment monitoring program specified in the tentative MRP is applicable to all entities that will be discharging to the OOO any time during the July 1, 2003 through June 30, 2004 sampling period. This sampling period has also been included in the NPDES permits for the other dischargers currently using the OOO. These dischargers include the City of Oceanside's wastewater treatment plants (Order No. 2000-11) and Fallbrook Public Utilities District's Treatment Plant No. 1 (Order No. 2000-12). Although the NIMO facility is expected to start discharging to the OOO in the Fall of 2003, IDEC is jointly responsible for the receiving water/sediment monitoring that will be conducted during the July 1, 2003 through June 30, 2004 period

No changes will be made to the MRP in response to Comment 8.